REMARKS/ARGUMENTS

Claims 1, 2, 4, 6-18, 49-52 and 60 are pending in the instant application. Claims 2, 4 and 11-18 have been withdrawn. Applicants respectfully request rejoinder of these claims. Claims 3, 5, 19-22, 45-48 and 53 have been canceled herein. Applicants reserve the right to pursue the subject matter of these claims in a divisional application. Applicants have amended claims 1, 2, 4, 6-11, 15-18, 49 and 51. Support for these amendments can be found in the claims as previously presented and at paragraphs 28, 47 and 92 of the instant specification. Applicants have also added new claim 60. Support for new claim 60 can be found, for example, at paragraph 47 of the instant specification. No new matter has been added.

Information Disclosure Statement

The Examiner described various deficiencies in the Information Disclosure Statement (IDS) filed on June 26, 2006. Applicants have resubmitted the art cited in the June 26, 2006 IDS in a supplemental IDS filed herewith.

Rejections under 35 U.S.C. § 102

The Examiner has rejected claims 1, 3, 5-10 and 45-53 under 35 U.S.C. § 102(a) for being anticipated by Imai *et al.* Ped. Nephrol. 17:790-794 (2002) ("Imai"). The Examiner argued that Imai teaches that therapeutic compositions of bone marrow contain mesenchymal stem cells and that transplantation of these cells into mammals results in the *in vivo* differentiation of the cells into renal cell types. The Examiner further alleged that Imai teaches that bone marrow transplantation can be used for accelerating regeneration of injured tissues and for the treatment of renal disease. Applicants respectfully traverse.

To anticipate a claim, the reference must teach every element of the claim.[1] Applicants submit that Imai does not teach the treatment of kidney dysfunction in a subject in need thereof. The Examiner refers to pages 792-793 of Imai as containing teachings of using bone marrow transplantation for the treatment of renal diseases.[2] Page 792 of Imai teaches the administration of green fluorescent protein (GFP) transfected bone marrow cells to rats with anti-Thy1 antibody

[1] *See* MPEP § 2131.
[2] *See* page 5 of the Office action.

mediated nephritis (Thy1 nephritis).[3] Imai also teaches that Thy1 nephritis causes disruption of normal mesangial cells.[4] Glomerular remodeling occurs, restoring the original structure in 8 weeks.[5] GFP positive cells are found in the glomeruli when they are administered during this remodeling period.[6] However, Imai does not teach a control in which rats that are not administered the bone marrow cells have a worse clinical outcome than the rats that were administered the cells. Likewise the teachings referred to in Imai from Paulsom, Lagaaij and Ying also lack controls and merely show that genetically labeled bone marrow cells persist in the kidney when administered to mammals.[7] Thus, Imai does not teach the administration of a therapeutic amount of mesenchymal stem cells, because no therapeutic effect is shown. For the same reason, Imai also does not teach the treatment of a kidney dysfunction. Moreover, Imai does not teach a mammal in need of treatment, because the Thy1 nephritis resolves without treatment in 8 weeks. The only mention of treatment in Imai states that "committed cells from any stem cell source may be an excellent therapeutic tool."[8] There is no teaching in Imai to administer mesenchymal stem cells for the treatment of kidney dysfunction.

Moreover, Applicants have amended claim 1, from which claims 3, 5-10 and 45-50 depend, to specify that the mesenchymal stem cells are isolated. Imai does not teach the administration of isolated mesenchymal stem cells. Imai only teaches the administration of bone marrow derived stem cells comprising both mesenchymal stem cells and, at least, hematopoietic stem cells.[9] Thus, Imai cannot anticipate claims 1, 3, 5-10 and 45-50.

Also, Applicants have amended claim 51, from which claims 52 and 53 depend, to state that the active ingredient consists essentially of mesenchymal stem cells. Imai only teaches the administration of bone marrow derived stem cells comprising both mesenchymal stem cells and, at least, hematopoietic stem cells.[10] Thus, Imai cannot anticipate claims 51-53.

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[3] *See* Imai at page 792, column 1.
[4] *Id.*
[5] *Id.*
[6] *Id.*
[7] *Id.* at bridging paragraph and column 2 first and second paragraphs.
[8] *Id.* at column 2, third paragraph.
[9] *Id.* at page 790, right column.
[10] *Id.* at page 790, right column.

Imai does not teach each and every limitation of claims 1, 3, 5-10 and 45-53 and thus cannot anticipate them. Thus, Applicants respectfully request that this rejection be withdrawn.

The Examiner has rejected claims 51-53 under 35 U.S.C. § 102(b) for being anticipated by Fibbe *et al.* Ann. N.Y. Acad. Sci. 938:9-17 (2002) ("Fibbe"). The Examiner argued that Fibbe teaches that therapeutic compositions of bone marrow contain mesenchymal stem cells and that transplantation of these cells into mammals results in the *in vivo* differentiation of the cells into renal cell types. Applicants respectfully traverse.

Applicants have amended claim 51, from which claims 52 and 53 depend, to state that the active ingredient consists essentially of mesenchymal stem cells. Fibbe only teaches the administration of bone marrow derived stem cells comprising both mesenchymal stem cells and, at least, hematopoietic stem cells. Thus, Fibbe cannot anticipate claims 51-53.

CONCLUSION

Applicant respectfully requests prompt examination in the application. If there are any questions regarding this Response, the Examiner is encouraged to contact the undersigned at the telephone number provided below.

Applicant believes no additional fees are due with the filing of this Response. However, if any additional fees are required or if any funds are due, the USPTO is authorized to charge or credit Deposit Account Number: **50-0311**, Customer Number: **30623**, Reference Number: **38447-201N01US**.

Respectfully submitted,

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